15.0 REFERENCE DATA USED FOR AN ASSESSMENT OF FETAX PERFORMANCE CHARACTERISTICS

15.1 Description of Available Reference Data Sources

In some FETAX testing circumstances (e.g., ecotoxicological hazard assessment), reference data for laboratory mammals may not be appropriate. In other testing situations, reference data from naturally occurring anuran populations may prove useful. Such data were not located. Reference laboratory mammal teratogenic data were sought from the several general sources and databases described in **Section 4.1** of this BRD. With very few exceptions, teratogenic data for laboratory mammals exposed to water/soil/sediment samples were not located, while relevant data for humans was nonexistent.

15.2 Reference Data

The laboratory mammal reference data for environmental samples are provided in **Appendix 4**. Laboratory mammal (mouse, rat, or rabbit) teratogenicity data were obtained for one of the 124 water/soil/sediment samples evaluated in FETAX. Where available, descriptive information on the types of malformations observed was included in the database.

Appropriate reference data for non-mammalian aquatic species was limited to a direct comparison between FETAX and a developmental assay using *Pimephales promelas* (fathead minnow) in one sediment study (Dawson et al., 1988) and in two-related soil extract studies (Fort et al., 1995; 1996). Appropriate reference data for other species were not located.

15.3 Availability of Original Reference Test Data

The availability of original test data for the reference assays is not known.

15.4. Reference Data Quality

The quality of any reference data in terms of accuracy and whether the studies were conducted in compliance with national/international Good Laboratory Practice (GLP) Guidelines is not known.

15.5 Availability and Use of Human Teratogenicity Data

No human teratogenicity data for the water/soil/sediment samples tested in FETAX were located.

15.6 Section 15 Conclusions

It is suggested that future assessments of FETAX for evaluating developmental hazards in water/soil/sediment samples include tests on at least one reference species. Such studies should follow standardized protocols for the reference species. It is recommended also that GLP guidelines be followed.